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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,242	06/18/2002	Thomas Gilchrist	8830-20	1401
7590 08/30/2004				
DOUGLAS E. DENNINGER TYCO HEALTHCARE GROUP LP 15 HAMPSHIRE STREET MANSFIELD, MA 02048			EXAMINER NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/069,242	<b>Applicant(s)</b> GILCHRIST ET AL.	
	<b>Examiner</b> David M. Naff	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,9-16,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,9-16,18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/16/02 01-22-02</u> | 6) <input type="checkbox"/> Other: _____  |

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#### **DETAILED ACTION**

A preliminary amendment of 6/18/02 amended claims 3-6, 8-10, 12, 14, 16 and 18.

A second preliminary amendment of 5/28/04 amended claims 1, 2, 6, 9-13 and 19, and canceled claims 3, 8 and 17.

Claims examined on the merits are 1, 2, 4-7, 9-16, 18 and 19, which are all claims in the application.

The copies of the PCT application papers of which the present application is a 371 do not contain copies of the foreign priority applications filed in the United Kingdom. Copies of the foreign priority applications filed in the PCT application must be submitted to obtain benefit of the filing dates of the applications.

#### ***Specification***

The disclosure is objected to because of the following informalities: the specification fails to contain headings designating different sections.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-Reference to Related Applications.

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- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).
- (e) Background of the Invention.
  - 1. Field of the Invention.
  - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

The following suggestions are made.

Page 1,

above line 3 insert --

BACKGROUND OF THE INVENTION

- 1. Field of the Invention

--.  
line 7, insert --

- 2. Description of the Related Art

--.  
Page 3, line 10, insert --

SUMMARY OF THE INVENTION

--.  
Page 9, line 7, insert --

BRIEF DESCRIPTION OF THE DRAWINGS

Page 13, line 10, insert --

DETAILED DESCRIPTION OF THE INVENTION

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--.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C.

5 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description

15 requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to disclose a process as required by claims 18 and 19 of encouraging growth of living tissue using the substrate of claim 1 when the substrate contains at least a portion of its surface coated with living cells as now required by amended claim 1. Disclosure is not found of using tissue and cells coated on the substrate together in the same process.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C.

112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is confusing by requiring a metallic ion or boron-containing compound as an additive since claim 1 requires a metallic ion or boron-containing compound. It is uncertain as to the relationship of the metallic ion or boron-containing compound in claim 11 to that in claim 1.

Claim 18 is confusing and unclear as to the process required by reciting only a single step of providing a substrate. More would be required to perform the process than merely providing the substrate of claim 1. It is uncertain as to the relationship of the tissue to the substrate and cells of claim 1. Is the substrate combined with tissue and culturing carried out, or are some other steps carried out.

Claim 19 is confusing and unclear in not having antecedent basis for an aqueous medium in line 2. It is uncertain as to the relationship of the aqueous medium to the tissue and substrate in claim 18, and it is uncertain as to steps used to deliver the metal ions or boron.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-7, 9-12, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnie et al in view of Gilchrist et al (WO 98/54104), and if necessary in further view of Beaver et al (4,748,121).

The claims are drawn to a cell culture growth substrate comprising a water-soluble glass matrix having at least a portion of its surface coated with living cells and containing at least one metallic ion or boron-containing compound.

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Burnie et al disclose using a water-soluble glass substrate in monolayer cell culture (paragraph bridging pages 244 and 245). The water-soluble glass is the same as presently claimed except for containing boron-containing compound.

5 Gilchrist et al disclose water-soluble glass fibers containing boron (page 8, lines 18-20) and silver ions (page 9, lines 8-13).

Beaver et al disclose immobilizing biochemically active material such as cells (col 3, lines 17-23) on porous glass fibers prepared from a composition containing silica, boric oxide, alkali metal oxide and aluminum oxide (paragraph bridging cols 5 and 6).

It would have been obvious to provide a compound containing boron in the soluble glass of Burnie et al in view of Gilchrist et al preparing soluble glass containing boron, and if needed in further view of Beaver et al disclosing preparing glass for immobilizing cells from a composition containing boron. Monolayer culture as disclosed by Burnie et al will result in the glass being coated with cells. Sodium in the glass of Burnie et al will provide a metallic ion required by claim 1 as an alternative to the boron-containing compound. Furthermore, Gilchrist et al (page 9, lines 8-36) would have suggested metallic ions in addition to sodium ions. The conditions of dependent claims would have been matters of choice depending on individual preference in view of the disclosures of the references. The glass of Burnie et al contains phosphorus pentoxide as in claim 5, and can be a phosphate glass (page 9, line 8-9) as in claim 4. The glass of Burnie et al also contains an oxide as in

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claims 6 and 7, and the glass will inherently have a dissolution rate as in claim 9 and enable controlled release as in claim 10. Gilchrist et al (page 4, line 32), as well as Burnie et al (page 244, right col, third complete paragraph), and if needed Beaver et al suggest fibers as in claim 12. The methods of claims 18 and 19 are suggested by Burnie et al and Gilchrist et al disclosing the glass dissolving, and Gilchrist et al disclosing the release of silver. Selecting an amount of metal ion release as in claim 19 would have been a matter of individual preference. Moreover, Gilchrist et al suggest (page 9, lines 30-31) the amount of metal ion release as in claim 19.

***Claim Rejections - 35 USC § 103***

Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1, 2, 4-7, 9-12, 18 and 19 above, and further in view of Ducheyne et al (5,811,302).

Claim 13 requires glass fibers sintered together to form a mat. Claims 14 requires glass particles which are sintered together in claim 15 and are of a specific size in claim 16.

Ducheyne et al disclose (col 4, lines 1-10) sintering glass particles to form a substrate for cell culture.

It would have been obvious to form the glass of Burnie et al, when modified as set forth above, as a sintered non-woven mat or sintered particles in view of Burnie et al disclosing (page 244, right col in the paragraph noted above) various forms including powder, fiber and woven cloth, and Gilchrist et al disclosing glass wool (page

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4, line 15), and Ducheyne et al disclosing sintering glass particles.

A powder will have a particle size within the range of claim 17.


**Conclusion**

Any inquiry concerning this communication or earlier

5 communications from the examiner should be directed to David M. Naff  
whose telephone number is 571-272-0920. The examiner can normally be  
reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,  
the examiner's supervisor, Mike Wityshyn can be reached on 571-272-  
10 0926. The fax phone number for the organization where this  
application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be  
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PAIR system, contact the Electronic Business Center (EBC) at 866-217-  
20 9197 (toll-free).

  
David M. Naff  
Primary Examiner  
Art Unit 1651